REMARKS

Claims 1 and 15-17 have been amended to affirmatively recite, amongst other things, that the claimed compositions have a brittle shell in an amount of from about 20% to about 50% of the total weight of the texture masking oral dosage form and a thickness of from about 500 μm to about 3000 μm. Support for these amendments can be found throughout the specification at, for example, paragraph 35 and Examples 1- 4.

These amendments were made in view of the disclosures of Lee and Mehta set forth by the Examiner in making out the obviousness rejection.

In addition, claims 1 and 16 were amended to correct the claimed weight ratio. Support for these amendments can be found throughout the specification at, for example, paragraph 29.

It is submitted that no new matter has been added by the above amendments.

Obviousness Rejection

Claims 1-25 were rejected under 35 USC §103(a) as being unpatentable over US Pat. No. 6,060,078 ("Lee") in view of US Pat. No. 4,800,087 ("Mehta") (Paper No. 20061108 at 2.)

For the reasons set forth below the rejection, respectfully is traversed.

The disclosures of Lee and Mehta set forth in previous papers submitted by Applicant in this Application are incorporated herein by reference.

In making the rejection, the Examiner asserted that

> Lee teaches a chewable pharmaceutical dosage form comprising of a core containing an active ingredient, and an outer layer (See Figure 2). The dosage form demonstrates improved organoleptic properties when chewed, such as taste (See Column 1, Lines 47-52). The core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin (See Column 2, Lines 29-33). In addition, gelatin may be used in either the core or outer layer to maintain hardness and extension property in the dosage form (See Column 2, Lines 59-61). The outer layer may take a variety of forms, including hard candy (See Column 2, Lines 34-42). Acetaminophen is listed as a possible active ingredient in the core (See Column 2, Lines 9-18). In addition, Lee contains what the examiner will interpret as an enabling disclosure of a dosage form with a unitary core (See Figure 2; and MPEP § 2125). The disclosed invention has the advantage of having an improved chewing property, which the examiner broadly interprets as having a texture masking property, in addition to having a taste masking property (See Column 3, Lines 53-58).

(Paper No. 20061108 at 2-3.)

The Examiner acknowledged, however, that Lee differs from the presently claimed invention in that Lee does not "teach the use of ibuprofen" and "it does not expressly disclose particle sizes of the active agent." (*Id.* at 3.)

To fill the acknowledged gap, the Examiner relied upon

Mehta teaches a chewable, taste-masked pharmaceutical dosage form, preferably in the form of a tablet (See Column 1, Lines 6-28). The components of this dosage form consist of taste-masked microcapsules, which may then be prepared as chewable tablets. The microcapsules themselves comprise a polymeric coating that masks the taste of the active ingredient, and a pharmaceutical core (See Column 4, Lines 4-12; and Examples 1 and 2). In one embodiment, the polymeric coating may be composed of a low-temperature film-forming polymer that produces a film at temperatures below 25°C., in order to produce microcapsules ranging in size from 10 microns to 1.5 mm in diameter (See Column 5, Lines 49-66). Acetaminophen and ibuprofen are listed among suitable drugs for use in the reference (See Column 7, Lines 31-48; and Claims 11 and 12). Diluents acceptable for use in the microcapsule core include gelatin (See Column 7, Line 59 to Column 8, Line 12). In the given examples, the preferred size of the uncoated acetaminophen particles used lies in the range of 150 to 300 microns (See Column 10, Lines 45-47). The reference also teaches that the coated pharmaceutical cores may then be encapsulated in a hard gelatin capsule or further coated with candy (See Column 9, Lines 35-40).

(Paper No. 20061108 at 3.)

The Examiner concluded that

> It would be obvious to one of ordinary skill in the art to combine the teachings of Lee and Mehta into the objects of the instant application. Both the Lee and Mehta patents deal with the administrations of drugs in pharmaceutical compositions with improved organoleptic properties. Therefore, one of ordinary skill would be motivated to incorporate the microcapsules disclosed in Mehta into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the drug. As Mehta states that the disclosed compositions may be incorporated into chewable tablets, in the view of the examiner, this disclosure provides sufficient guidance to one of ordinary skill in the art to incorporate them into the chewable dosage form taught in Lee. As such, it is the position of the examiner that one of ordinary skill in the art could combine the disclosures of the prior art with a reasonable expectation of success.

(Paper No. 20061108 at 4.)

> The adjustment and optimization of parameters such as hardness of the soft core and the weight ratio of active agent particles are considered by the examiner to be well within the purview of one of ordinary skill in the art. Therefore, claim limitations drawn to such features are not considered by the examiner to impart a patentable quality unto the instantly claimed invention.

(*Id.* at 4).

Obviousness cannot be based upon speculation. Nor can obviousness be based upon possibilities or probabilities. Obviousness *must* be based upon facts, "cold hard facts." When a conclusion of obviousness is not based upon facts, it cannot stand.

Mehta's disclosure resulted in coated particles designed to prevent **release drugs during chewing.** It appears that such prevention avoided contact of acetaminophen in the mouth during chewing, thereby avoiding a bitter taste. Additionally, it is not seen where Mehta disclosed any facts to indicate that texture masking was also addressed.

It appears that Lee disclosed a different technique for taste-masking. Lee discloses a core containing a medicament in a state of jelly or chewable base, and an

outerlayer of chewable base wrapping the core. Lee did not disclose that the particles used therein were coated. It is submitted that one of ordinary skill in the art would have disclosed coated particles if coated particles were in fact used to make the disclosed composition. Lee therefore used uncoated particles. Because Lee used uncoated particles, there appears to be no motivation for one seeking to solve the problem of taste masking that Mehta and Lee were attempting to solve by using large particles because such particles would necessarily introduce a new problem, i.e., grittiness, into the composition. Additionally, it is not seen where Mehta disclosed any facts to indicate that texture masking was also addressed.

Further, its is not seen where the Lee or Mehta, alone or in combination, disclose or provide any motivation to product a dosage form as claimed having the amended coating weight and thickness. For this additional reason, it is believed that the rejection is improper and should be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Accordingly, entry of the claims and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

Respectfully submitted,

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